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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/684,847      | 10/14/2003  | James F. Zucherman   | KLYC-01056USD       | 3522             |

23910 7590 06/01/2006

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| EXAMINER |
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PHILOGENE, PEDRO

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| ART UNIT | PAPER NUMBER |
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3733

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/684,847

Applicant(s)

ZUCHERMAN ET AL.

Examiner

Pedro Philogene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-29 is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-13, 17-20, 37-39, 42-45 and 3033 is/are rejected.
- 7) ☒ Claim(s) 5-7, 14-16, 34-36, 40 and 41 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/7/05, 12/21/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3,4, 9-11,13,18-20,30, 32-33,38,39,42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al (6,190,414).

With respect to the claims, Young et al disclose an implant comprising a spacer (104) that is adapted to fit between spinous process; and a means (124) for adjusting the height of the spacer in order to adjust the spacing between the spinous process. The spacer has a first portion and a second portion which are movable relative to each other; as best seen in FIG.1. the first and second portions connected by a hinge; as best seen in FIG.1, the adjusting means including a jack; as best seen in FIG.3, the jack is adjusted by turning a screw; as best seen in FIG.3, in one of the first and second directions.

With respect to the claims, the implant comprising a body having a shaft (162) extending therefrom, a spacer (104 pivotally mounted on the body, the spacer including a first and second portion; as best seen in FIG.3, a mechanism (124) positioned between the first portion and the second portion that can adjust a space between the first and the second portion, as best seen in FIGS.10-13.

The method steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3,4, 11,13,30, 32-33,39,43 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackson (6,454,807).

With respect to the claims, Jackson discloses an implant comprising a spacer (1) that is adapted to fit between spinous process; and a means (84) for adjusting the height of the spacer in order to adjust the spacing between the spacing between the spinous process. The spacer has a first portion (10) and a second portion (11), which are movable relative to each other; as best seen in FIG.1., the first and second portions connected by a hinge; as best seen in FIG.1.

With respect to the claims, the implant comprising a body (12) having a shaft (83) extending therefrom, a spacer pivotally mounted on the body, the spacer including a first and second portion (10,11); as best seen in FIG.3, a mechanism (84) positioned between the first portion and the second portion that can adjust a space between the first and the second portion, as best seen in FIG.6.

The method steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2,8,1217,31,37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (6,190,414).

With respect to the claims, it is noted that Young et al did not teach of an elliptical shape implant or a first portion and second portion having a curved surface; as claimed by applicant. However, absent from any conclusive statements concerning unexpected or unobvious results obtained from these particular configurations; these are nothing more than one of numerous configurations a person of ordinary skill in the art would find obvious for the purpose of providing a surface to the implant. in re Dailey, 149 USPQ 47 (CCPA 1976).

#### ***Allowable Subject Matter***

Claims 5-7, 14-16,34-36,40,41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 21-29 are allowed.

#### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


|           |         |                    |
|-----------|---------|--------------------|
| 6,773,460 | 08-2004 | Jackson            |
| 5,554,191 | 09-1996 | Lahille et al.     |
| 6,375,682 | 04-2002 | Fleischmann et al. |

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pedro Philogene  
May 25, 2006



PEDRO PHILOGENE  
PRIMARY EXAMINER